REMARKS

Amendments

Claims 10 and 19 are cancelled without prejudice or disclaimer.

Dependent claims are made dependent on Claim 27, which uses the "consisting of" language with respect to the structure of the oral delivery device. Thus, this claim excludes, for example, a soft capsule from the device.

Claim 13 is rewritten in independent form using the "consisting of" terminology and provides that the shaped core has a powder on its surface. This embodiment likewise excludes the presence of a soft capsule from the device. The scope of claim 13 is not broadened. Thus, entering this amendment raises no new issues.

The Rejection under 35 USC § 103

Claims 10-19 and 27 were rejected as allegedly unpatentable over Mansanobu, JP 10226650, in view of Takada, US 5637319.

Mansanobu on page 13, in the paragraph labeled [0025], describes the invention taught by the reference as

> The preparation of the present invention comprises glycyrrhizin or a salt thereof and a middle-chain fatty acid or a salt thereof as absorption promoter solubilized in a solubilizing agent, and an enteric coating film applied thereon.

Nowhere does Mansanobu describes the invention of the reference as containing glyceride. The Office Action alleges that the reference teaches an oral preparation containing glycyrrhizin and a middle chain fatty acid (capric acid), a solubilizing agent such as propylene glycol, polyethylene glycol, or nonionic surfactant. Applicants agree with these allegations, but note that glyceride is not mentioned in the allegations. Thus, Mansanobu does not teach that the invention described therein contains glyceride.

The invention of the reference is directed to a solubilized form of glycyrrizin in a composition. Mansanobu on page 7, lines 1-6, teaches that

> delivery of a drug and an absorption promoter to the large intestine in solid state was not effective to improve the absorption sufficiently. The present invention has solved this problem by solubilizing the solid drug and absorption promoter in a solubilizing agent.

Thus, nowhere does the primary reference suggest that the core material should solidify. Instead, the reference teaches that the prior art problems were solved by solubilizing. See for

example, the passage on page 7, paragraph labeled [0010], which immediately follows the previously cited passage.

> Solubilization of glycyrrhizin and absorption promoter has been thought very difficult as is apparent from the above-cited prior art ... wherein a lipid emulsion or a complex mixture in lipid is used. The inventors have succeed the solubilization using the solubilizing agent of the present invention.

Additionally, all the examples of Mansanobu according to the invention are in the form of solutions. The comparative examples are palletized powder, e.g., are solid. See examples and comparative examples. Mansanobu teaches that the examples in accord with the invention, e.g., the ones solubilized, exhibited very excellent absorption over the preparations of the comparative examples. See page 22, paragraph labeled [0052].

Furthermore, even if the core material may solidify after the solubilizing takes place, which is not admitted, or taught, or suggested by the reference, the resultant product of Mansanobu would not lead, alone or in combination with the secondary reference, to the claimed invention. Mansanobu teaches that the core material solution is processed into a soft capsule. See example 7-1. Thus, even if the material in the core is to solidify at a later time after the device is prepared, said device will always contain a soft capsule around the allegedly possible shaped core.

Additionally, nothing in the reference teaches or suggests that the core material should melt or liquefy at the body temperature. Nothing in the reference teaches or suggests the selection of core material that satisfies all the claimed features of the core material.

Mansanobu also describes various prior art and on page 5, in the first paragraph, describes broadly a composition of glycirrhizin and a fatty acid glyceride which is coated with an enteric film. This disclosure however is not the invention of Mansanobu and, also, is very broad. This disclosure may contain embodiments wherein the core material may possibly overlap the core material of the present invention if all the right choices are made within the broad disclosure, for which choices no motivation is present. However, that is not enough or adequate to support an obviousness rejection. Also, there is no suggestion to combine these teachings with the actual Mansanobu invention. The reference does not teach or suggest a core material that forms a shaped core and also melts at or about the body temperature. No motivation for the required selections is provided by the reference to the presently claimed core.

Additionally, both the invention of Mansanobu and the prior art described on page 5

are coated with an enteric coating. Nothing in the reference teaches or suggests that other types of coating would be useful or desired over the disclosed compositions. There is no teaching or suggestion in this reference to motivate one of ordinary skill in the art to use coatings other than enteric.

Takada teaches a variety of capsules, one of which is an ethylcellulose capsule. Takada teaches that

> if the drug is liquid or is used as solution or suspension, (1) coat the inner surface of a whole gelatin capsule with EC by introducing EC solution through a pore made at the top of gelatin capsule followed rotating the capsule at horizontal position and evaporating the solvent, (2) fill a drug solution dissolved in a solvent such as propylene glycol (PG) into the EC coated gelatin capsule through a pore at the top of the capsule, (3) close the pore by the drop of EC glue.

See column 8, lines 18-27. Thus, if the solution of Mansanobu were to be filled into a capsule taught by Takada instead of the soft capsule, e.g., use Takada's ethylcellulose capsule in Mansanobu's core, said capsule would also contain a gelatin capsule, which is excluded by the claim language.

Takada also teaches that the capsule can be formed by "coating the inner or outer surface of a conventional gelatin capsule body and dissolving gelatin in warm water." See column 8, lines 15-18, referring to preparation described as in (A)(1), which is located on column 7, lines 59-64. While the reference does not expressly state on column 8, lines 15-18, that this embodiment applies to solid cores during processing, it appears to be the case in view of the separate treatment of core material that is "liquid or is used as solution or suspension," and in further view of the remainder part of the preparation described in (A) on column 7, line 64 to column 8, line 5, which teaches, for example, in (A)(3) to insert a tablet. Thus, one of ordinary skill in the art would not have used this capsule for the suspension of the primary reference. If the solution of the primary reference is already in a soft capsule and is then placed into this ethylcellulose capsule, the resultant product would be excluded by the claims as it would contain a soft capsule.

Nowhere does Takada teach or suggest processing a liquid core material directly (meaning without the presence of a soft or gelatin capsule) into an ethylcellulose capsule.

While Takada describes a variety of capsules, nowhere does this reference teach or suggest that any or these capsules are or should be interchangeable with enteric coatings, which is the coating the primary reference taught. This reference also lacks the motivation to

replace the enteric coating of the primary reference with an ethylcellulose capsule. As stated in Takada, an ethylcellulose capsule is insoluble in water and, thus, distinct from an enteric coating which dissolves at a certain pH.

With respect to claim 13, none of the references teach or suggest a device, which contains a powder on the surface of the shaped core. Thus, this claim is not obvious for this additional reason.

For all the foregoing reasons, the combination of these two references do not teach or suggest to one of ordinary skill in the art the claimed invention.

Applicants respectfully request the rejoinder of the process of making claims which are directed to the preparation of the devices of the product claims. Such a rejoinder is mandated by MPEP § 821.04, e.g., "process claims which either depend from or include all the limitations of the allowable product will be rejoined." The claimed method is illustrated, but not limited to, for example, the process of example 2 of the specification, e.g., pouring the core material into a mold, cooling the same to obtain a solid shaped core, and covering the shaped core, which is not covered by a soft capsule, with ethylcellulose. Nothing in the prior art suggests steps analogous to these, which result in a device as claimed.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Filed: April 19, 2004

AJZ/CH(pdr):K:\AKA\269\Reply Apr 04.doc